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Bifenox (Methyl-5-(2,4-Dichlorophenoxy)-2-Nitrobenzoate); Pesticide Registration Standard

(U.S.) Environmental Protection Agency
Washington, DC

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United States
Environmental Protection
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Office of
Pesticides and Toxic Substances
Washington DC 20460

December 1981

Pesticides

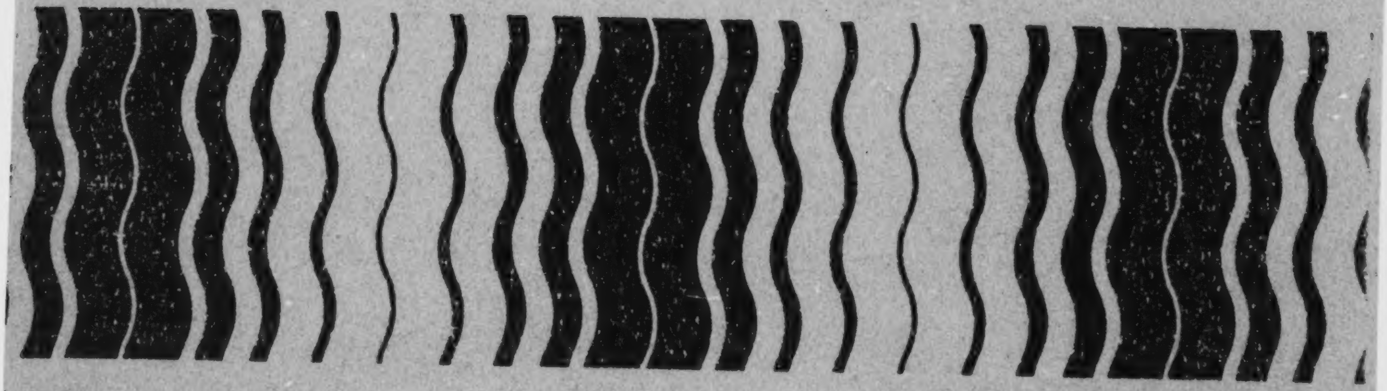
EPA

PB83-140434

Bifenox

Methyl 5-(2,4-dichlorophenoxy) -2-nitrobenzoate

Pesticide Registration Standard



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BIFENOX

Pesticide Registration Standard

June, 1981

Office of Pesticides and Toxic Substances

Environmental Protection Agency
401 M Street, SW
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BIFENOX

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Chapter 1
HOW TO REGISTER UNDER A REGISTRATION STANDARD

Organization of the Standard
Purpose of the Standard
Requirement to Re-register Under the Standard
"Product Specific" Data and "Generic" Data
Data Compensation Requirements under FIFRA 3(c)(1)(D)
Obtaining Data to Fill "Data Gaps"; FIFRA 3(c)(2)(B)
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Organization of the Standard

This first chapter explains the purpose of a Registration Standard and summarizes the legal principles involved in registering or re-registering under a Standard. The second chapter sets forth the requirements that must be met to obtain or retain registration for products covered by this particular Registration Standard. In the remaining chapters, the Agency reviews the available data by scientific discipline, discusses the Agency's concerns with the identified potential hazards, and logically develops the conditions and requirements that would reduce those hazards to acceptable levels.

Purpose of the Standard

Section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provides that "no person in any State may distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive (and having so received) deliver or offer to deliver, to any person any pesticide which is not registered with the Administrator [of EPA]." To approve the registration of a pesticide, the Administrator must find, pursuant to Section 3(c)(5) that:

> "(A) its composition is such as to warrant the proposed claims for it;
> (B) its labeling and other material required to be submitted comply with the requirements of this Act;
> (C) it will perform its intended function without unreasonable adverse effects on the environment; and
> (D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment."

In making these findings, the Agency reviews a wide range of data which registrants are required to submit, and assesses the risks and benefits associated with the use of the proposed pesticide. But the established approach to making these findings has been found to be defective on two counts:

First, EPA and its predecessor agency, the United States Department of Agriculture (USDA), routinely reviewed registration applications on a 'product by product' basis, evaluating each product-specific application somewhat independently. In the review of products containing similar components, there was little opportunity for a retrospective review of the full range of pertinent data available in Agency files and in the public literature. Thus the 'product by product' approach was often inefficient and sometimes resulted in inconsistent or incomplete regulatory judgments.

Second, over the years, as a result of inevitable and continuing advances in scientific knowledge, methodology, and policy, the data base for many pesticides came to be considered inadequate by current scientific and regulatory standards. Given the long history of pesticide regulation in several agencies, it is even likely that materials may have been lost from the data files. When EPA issued new requirements for registration in 1975 (40 CFR 162) and proposed new guidelines for hazard testing in 1978 (43 FR 29686, July 10, 1978 and 43 FR 37336, August 22, 1978), many products that had already been registered for years were being sold and used without the same assurances of human and environmental safety as was being required for new products. Because of this inconsistency, Congress directed EPA to re-register all previously registered products, so as to bring their registrations and their data bases into compliance with current requirements [See FIFRA Section 3(g)].

Facing the enormous job of re-reviewing and calling-in new data for the approximately 35,000 current registrations, and realizing the inefficiencies of the 'product by product' approach, the Agency decided that a new, more effective method of review was needed.

A new review procedure has been developed. Under it, EPA publishes documents called Registration Standards, each of which discusses a particular pesticide active ingredient. Each Registration Standard summarizes all the data available to the Agency on a particular active ingredient and its current uses, and sets forth the Agency's comprehensive position on the conditions and requirements for registration of all existing and future products which contain that active ingredient. These conditions and requirements, all of which must be met to obtain or retain full registration or re-registration under Section 3(c)(5) of FIFRA, include the submission of needed scientific data which the Agency does not now have, compliance with standards of toxicity, composition, labeling, and packaging, and satisfaction of the data compensation provisions of FIFRA Section 3(c)(1)(D).

The Standard will also serve as a tool for product classification. As part of the registration of a pesticide product, EPA may classify each product for "general use" or "restricted use" [FIFRA Section 3(d)]. A pesticide is classified for "restricted use" when some special regulatory restriction is needed to ensure against unreasonable adverse effects to man or the environment. Many such risks of unreasonable adverse effects can be lessened if expressly designed label precautions are strictly followed. Thus, the special regulatory restriction for a "restricted use" pesticide is usually a requirement that it be applied only by, or under the supervision of, an applicator who has been certified by the State or Federal government as being competent to use pesticides safely, responsibly, and in accordance with label directions. A restricted-use pesticide can have other regulatory restrictions [40 CFR 162.11(c)(5)] instead of, or in addition to, the certified applicator requirement. These other regulatory restrictions may include such actions as seasonal or regional limitations on use, or a requirement for the monitoring of residue levels after use. A pesticide classified for "general use," or not classified at all, is available for use by any individual who is in compliance with State or local regulations. The Registration Standard review compares information about potential adverse effects of specific uses of the pesticide with risk criteria listed in 40 CFR 162.11(c), and thereby determines whether a product needs to be classifed for "restricted use." If the Standard does classify a pesticide for "restricted use," this determination is stated in the second chapter.

Requirement to Re-register Under the Standard

FIFRA Section 3(g), as amended in 1978, directs EPA to re-register all currently registered products as expeditiously as possible. Congress also agreed that re-registration should be accomplished by the use of Registration Standards.

Each registrant of a currently registered product to which this Standard applies, and who wishes to continue to sell or distribute his product in commerce, must apply for re-registration. His application must contain proposed labeling that complies with this Standard.

EPA will issue a notice of intent to cancel the registration of any currently registered product to which this Standard applies if the registrant fails to comply with the procedures for re-registration set forth in the Guidance Package which accompanies this Standard.

"Product Specific" Data and "Generic" Data

In the course of developing this Standard, EPA has determined the types of data needed for evaluation of the properties and effects of products to which the Standard applies, in the disciplinary areas of Product Chemistry, Environmental Fate, Toxicology, Residue Chemistry, and Ecological Effects. These determinations are based primarily on the data Guidelines proposed in 1978 (43 FR 29686, July 10, 1978, and 43 FR 37336, August 2, 1978), as applied to the use patterns of the products to which this Standard applies. Where it appeared that data from a normally applicable Guidelines requirement was actually unnecessary to evaluate these products, the Standard indicates that the requirement has been waived. On the other hand, in some cases studies not required by the Guidelines may be needed because of the particular composition or use pattern of products the Standard covers; if so, the Standard explains the Agency's reasoning. Data guidelines have not yet been proposed for the Residue Chemistry discipline, but the requirements for such data have been in effect for some time and are, the Agency believes, relatively familiar to registrants. Data which we have found are needed to evaluate the registrability of some products covered by the Standard may not be needed for the evaluation of other products, depending upon the composition, formulation type, and intended uses of the product in question. The Standard states which data requirements apply to which product categories. (See the second chapter). The various kinds of data normally required for registration of a pesticide product can be divided into two basic groups:

(A) data that are "product specific," i.e., data that relates only to the properties or effects of a product with a particular composition (or a group of products with closely similar composition); and

(B) "generic" data that pertain to the properties or effects of a particular ingredient, and thus is relevant to an evaluation of risks and benefits of all products containing that ingredient (or all such products having a certain use pattern), regardless of any such product's unique composition.

The Agency requires certain "product specific" data for each product to characterize the product's particular composition and physical/chemical properties (Product Chemistry), and to characterize the product's acute toxicity (which is a function of its total composition). The applicant for registration or re-registration of any product, whether it is a manufacturing-use or end-use product, and without regard to its intended use pattern, must submit or cite enough of this kind of data to allow EPA to evaluate the product. For such purposes, "product specific" data on any product other than the applicant's is irrelevant, unless the other product is closely similar in composition to the applicant's. (Where it has been found practicable to group similar products for purposes of evaluating, with a single set of tests, all products in the group, the Standard so indicates). "Product specific" data on the efficacy of particular end-use products is also required where the exact formulation may affect efficacy and where failure of efficacy could cause public health problems.

All other data needed to evaluate pesticide products concerns the properties or effects of a particular ingredient of products (normally a pesticidally active ingredient, but in some cases a pesticidally inactive, "inert," ingredient). Some data in this "generic" category are required to evaluate the properties and effects of all products containing that ingredient [e.g., the acute LD_{50} of the active ingredient in its technical or purer grade; see proposed 40 CFR 163.81-1(a), 43 FR 37355].

Other "generic" data are required to evaluate all products which both contain a particular ingredient and are intended for certain uses (see, e.g., proposed 40 CFR 163.82-1, 43 FR 37363, which requires subchronic oral testing of the active ingredient with respect to certain use patterns only). Where a particular data requirement is use-pattern dependent, it will apply to each end-use product which is to be labeled for that use pattern (except where such end-use product is formulated from a registered manufacturing-use product permitting such formulations) and to each manufacturing-use product with labeling that allows it to be used to make end-use products with that use pattern. Thus, for example, a subchronic oral dosing study is needed to evaluate the safety of any manufacturing-use product that legally could be used to make an end-use, food-crop pesticide. But if an end-use product's label specified it was for use only in ways that involved no food/feed exposure and no repeated human exposure, the subchronic oral dosing study would not be required to evaluate the product's safety; and if a manufacturing-use product's label states that the product is for use only in making end-use products not involving food/feed use or repeated human exposure, the subchronic oral study would not be relevant to the evaluation of the manufacturing-use product either.

If a registrant of a currently registered manufacturing-use or end-use product wishes to avoid the costs of data compensation [under FIFRA Section 3(c)(1)(D)] or data generation [under Section 3(c)(2)(B)] for "generic" data that is required only with respect to some use patterns, he may elect to delete those use patterns from his labeling at the time he re-registers his product. An applicant for registration of a new product under this Standard may similarly request approval of only certain use patterns.

Data Compensation Requirements under FIFRA 3(c)(1)(D)

Under FIFRA Section 3(c)(1)(D), an applicant for registration, re-registration, or amended registration must offer to pay compensation for certain existing data the Agency has used in developing the Registration Standard. The data for which compensation must be offered is all data which is described by all the following criteria:

(1) The data were first submitted to EPA (or to its predecessor agencies, USDA or FDA), on or after January 1, 1970;

(2) The data were submitted to EPA (or USDA or FDA) by some other applicant or registrant in support of an application for an experimental use permit, an amendment adding a new use to a registration, or for re-registration, or to support or maintain in effect an existing registration;

(3) They are the kind of data which are relevant to the Agency's decision to register or re-register the applicant's product under the Registration Standard, taking into account the applicant's product's composition and intended use pattern(s);

(4) The Agency has found the data to be valid and usable in reaching regulatory conclusions; and

(5) They are not data for which the applicant has been exempted by FIFRA Section 3(c)(2)(D) from the duty to offer to pay compensation. (This exemption applies to the "generic" data concerning the safety of an active ingredient of the applicant's product, not to "product specific" data. The exemption is available only to applicants whose product is labeled for end-uses for which the active ingredient in question is present in the applicant's product because of his use of another registered product containing that active ingredient which he purchases from another producer).

An applicant for re-registration of an already registered product under this Standard, or for registration of a new product under this Standard, accordingly must determine which of the data used by EPA in developing the Standard must be the subject of an offer to pay compensation, and must submit with his application the appropriate statements evidencing his compliance with FIFRA Section 3(c)(1)(D).

An applicant would never be required to offer to pay for "product specific" data submitted by another firm. In many, if not in most cases, data which are specific to another firm's product will not suffice to allow EPA to evaluate the applicant's product, that is, will not be useful to the Agency in determining whether the applicant's product is registrable. There may be cases, however, where because of close similarities between the composition of two or more products, another firm's data may suffice to allow EPA to evaluate some or all of the "product specific" aspects of the applicant's product. In such a case, the applicant may choose to cite that data instead of submitting data from tests on his own product, and if he chooses that option, he would have to comply with the offer-to-pay requirements of Section 3(C)(1)(D)for that data.

Each applicant for registration or re-registration of a manufacturing-use product, and each applicant for registration or re-registration of an end-use product, who is not exempted by FIFRA Section 3(c)(2)(D), must comply with the Section 3(c)(1)(D) requirements with respect to each item of "generic" data that relates to his product's intended uses.

A detailed description of the procedures an applicant must follow in applying for re-registration (or new registration) under this Standard is found in the Guidance Package for this Standard.

Obtaining Data to Fill "Data Gaps"; FIFRA 3(c)(2)(B)

Some of the kinds of data EPA needs for its evaluation of the properties and effects of products to which this Standard applies have never been submitted to the Agency (or, if submitted, have been found to have deficiencies rendering them inadequate for making registrability decisions) and have not been located in the published literature search that EPA conducted as part of preparing this Standard. Such instances of missing but required data are referred to in the Standard as "data gaps".

FIFRA Section 3(c)(2)(B), added to FIFRA by the Congress in 1978, authorizes EPA to require registrants to whom a data requirement applies to generate (or otherwise produce) data to fill such "gaps" and submit those data to EPA. EPA must allow a reasonably sufficient period for this to be accomplished. If a registrant fails to take appropriate and timely steps to fill the data gaps identified by a section 3(c)(2)(B) order, his product's registration may be suspended until the data is submitted. A mechanism is provided whereby two or more registrants may agree to share in the costs of producing data for which they are both responsible.

The Standard lists, in the third chapter, the "generic" data gaps and notes the classes of products to which these data gaps pertain. The Standard also points out that to be registrable under the Standard, a product must be supported by certain required "product specific" data. In some cases, the Agency may possess sufficient "product specific" data on one currently registered product, but may lack such data on another. Only those Standards which apply to a very small number of currently registered products will attempt to state definitively the "product specific" data gaps on a 'product by product' basis. (Although the Standard will in some cases note which data that EPA does possess would suffice to satisfy certain "product specific" data requirements for a category of products with closely similar composition characteristics.)

As part of the process of re-registering currently registered products, EPA will issue Section 3(c)(2)(B) directives requiring the registrants to take appropriate steps to fill all identified data gaps -- whether that data in question is "product specific" or "generic" -- in accordance with a schedule.

Persons who wish to obtain registrations for new products under this Standard will be required to submit (or cite) sufficient "product specific" data before their applications are approved. Upon registration, they will be required under Section 3(c)(2)(B) to take appropriate steps to submit data needed to fill "generic" data gaps. (We expect they will respond to this requirement by entering into cost-sharing agreements with other registrants who previously have been told they must furnish the data.) The Guidance Package for this Standard details the steps that must be taken by registrants to comply with Section 3(c)(2)(B).

Amendment to the Standard

Applications for registration which propose uses or formulations that are not presently covered by the Standard, or which present product compositions, product chemistry data, hazard data toxicity levels, or labeling that do not meet the requirements of the Standard, will automatically be considered by the Agency to be requests for amendments to the Standard. In response to such applications, the Agency may request additional data to support the proposed amendment to the Standard, or may deny the application for registration on the grounds that the proposed product would cause unreasonable adverse effects to the environment. In the former case, when additional data have been satisfactorily supplied, and providing that the data do not indicate the potential for unreasonable adverse effects, the Agency will then amend the Standard to cover the new registration.

Each Registration Standard is based upon all data and information available to the Agency's reviewers on a particular date prior to the publication date. This "cut-off" date is stated at the beginning of the second chapter. Any subsequent data submissions and any approved amendments will be incorporated into the Registration Standard by means of addenda, which are available for inspection at EPA in Washington, D.C., or copies of which may be requested from the Agency. When all the present "data gaps" have been filled and the submitted data have been reviewed, the Agency will revise the Registration Standard. Thereafter, when the Agency determines that the internally maintained addenda have significantly altered the conditions for registration under the Standard, the document will be updated and re-issued for publication.

While the Registration Standard discusses only the uses and hazards of products containing the designated active ingredient(s), the Agency is also concerned with the potential hazards of some inert ingredients and impurities. Independent of the development of any one Standard, the Agency has initiated the evaluation of some inert ingredients of concern in a specific product to which the Standard applies, these ingredients will be pointed out in the Guidance Package.

II. REGULATORY POSITION

A. INTRODUCTION

This chapter presents the Agency's regulatory position on products which contain bifenox as the sole active ingredient and have the same use patterns as described in this Standard. The regulatory position adopted by the Agency incorporates a number of considerations. Foremost among these considerations is an analysis of the registrability of products containing bifenox based on the risk criteria found in Section 162.11(a) of Title 40 of the U.S. Code of Federal Regulations. The Agency's determination is presented below, and the rationale for this decision follows the position.

In addition to the basic regulatory decision and rationale, this chapter includes the following: criteria for the registration of bifenox products under the Standard; acceptable ranges and limits for product composition, acute toxicity, and use pattern/application method; required labeling; and tolerance reassessment.

A summary of data requirements is contained in Chapter III, Tables 1-3. Discussion of the data upon which this regulatory position is based is presented in each of the disciplinary chapters, (Chapters IV-VIII).

B. DESCRIPTION OF CHEMICAL

Bifenox is the common name for the herbicide methyl 5-(2,4-dichlorophenoxy)-2-nitrobenzoate. This herbicide is used for preemergent weed control on soybeans, corn and sorghum; pre- and postemergent use on rice, barley, wheat, and oats, and postemergent use on forest tree nursery seedbeds.

The trade name for this chemical is Modown^{R}. The Chemical Abstracts Registry (CAS) number for bifenox is 42576-02-03. This number was formerly 12680-11-4.

C. REGULATORY POSITION

The Agency has reviewed the data available to it on bifenox. As will be indicated in the Topical Discussions which follow, scientific data on bifenox products are limited. While a complete data base is available on the residue chemistry of bifenox, data on the physical/chemical properties, ecological effects, and environmental fate are limited, insufficient, or unavailable. Data needed to determine the toxicity of bifenox to humans are absent because the studies available to the Agency were conducted by Industrial Bio-Test Laboratories (IBT), see Chapter VI. Thus, much of the data needed to assess the hazard of bifenox to man and the environment do not now exist.

Based on review of the available scientific data obtained from the open literature as of May, 1981, and the data submitted by the registrant up through publication of this Standard,the Agency believes that none of the risk criteria found in Section 162.11(a) of Title 40 of the U.S. Code of Federal Regulations would be met or exceeded and that bifenox does not appear to cause unreasonable adverse effects with proper label directions and precautions. In accordance with FIFRA, the Agency's policy is not to cancel routinely the registration of products merely because it lacks data, or to withhold registration merely for the lack of data [See Section 3(C)(2)(B) and Section (3)(c)(7) of FIFRA]. Bifenox products as described in this Standard, therefore, may be registered for sale, distribution, reformulation and use in the United States subject to the the conditions imposed for data requirements. New products may be registered under this Standard and are subject to the same requirements. When the data gaps identified in this Standard are filled, the Agency will reassess the registration status of bifenox.

D. REGULATORY RATIONALE

Bifenox is a pre-emergent herbicide used to control a variety of weeds. The chemical is used also as a postemergent treatment on some agricultural sites. Bifenox was developed during the early 1970's by the Phosphorous Division of Mobil Chemical Company. This chemical has had appreciable use since then, with an annual estimated production of 2-3 million pounds.

Numerous gaps in the data base preclude completion of an assessment of the hazards and potential risks to humans and the environment as a result of exposure to Bifenox products.

Other than the data generated by IBT, toxicity data are not available on any bifenox products. Some data are available on the physical/chemical properties of bifenox, but several gaps exist in the product chemistry data base. There are limited data on the environmental fate and ecological effects of bifenox. Several of the submitted studies on ecological effects either did not meet Agency's guideline requirements due to deviations from acceptable protocols, or were IBT data which could not be included in the Standard (see Chapters III, VI and VIII).

A review of the studies sufficient to meet data requirements and those which failed to meet data requirements but which provided some level of qualitative information revealed no adverse effects of regulatory concern. Thus, the Agency does not have reason to believe that the use of bifenox will cause unreasonable adverse effects when used in compliance with proper label directions and precautions.

As noted in Chapter V on the fate of bifenox in the environment, some exposure can be expected from use of this pesticide, with the greatest potential occurring during mixing, loading, and spraying operations. However, data are not available to estimate the degree of such exposure. Exposure can be minimized by the use of gloves and protective clothing during mixing and loading and by following use and disposal directions currently found on the labels.

E. CRITERIA FOR REGISTRATION UNDER THE STANDARD

To be subject to this Standard, bifenox products must meet the following conditions:

(a) contain bifenox as the sole active ingredient or contain bifenox in a mixture which has the same use patterns described in this Standard;

(b) be within acceptable standards of product composition;

(c) be within acceptable acute toxicity limits;

(d) be labeled for acceptable end-uses; and

(e) bear required labeling.

Manufacturing-use bifenox products must bear label directions for formulation into acceptable end-uses.

Applicants for registration or reregistration of bifenox products subject to this Standard must comply with all terms and conditions described in this Standard, including commitment to fill data gaps on a time schedule specified by the Agency and, when applicable, offer to pay compensation to the extent required by 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, 7 U.S.C. 136(c)(1)(D) and 136(c)(2)(D). As discussed in Chapter I, applicants for registration under this Standard must contact the Agency for specific instructions, including updated information on data requirements and companies whose data must be cited and to whom compensation must be offered.

The only registrant that has submitted data in support of bifenox registrations, and has not waived rights to compensation for data, is Mobil Chemical Company.

Acceptable Ranges and Limits

a. Manufacturing-use Bifenox

1. Product Composition Standard

To be covered under this Standard, manufacturing-use bifenox products must contain bifenox as the sole active ingredient. Manufacturing-use bifenox products with any percentage of active ingredient with appropriate certification of limits are acceptable under this Standard.

2. Acute Toxicity Limits

The Agency will consider registration of manufacturing-use bifenox products in the following toxicity categories:

	I	II	III	IV
Acute oral toxicity	yes	yes	yes	yes
Acute dermal toxicity	yes	yes	yes	yes
Acute inhalation toxicity	yes	yes	yes	yes
Primary eye irritation	yes	yes	yes	yes
Primary dermal irritation	yes	yes	yes	yes

3. Use Patterns

To be covered under this Standard, manufacturing-use bifenox products must be labeled for formulation into end-use pesticides which are intended for terrestrial and aquatic applications.

b. End Use Bifenox - Wettable Powder, Emulsifiable Concentrate, Flowable

1. Product Composition Standard

End use bifenox products with any percentage of active ingredient are acceptable under this Standard with appropriate certification of limits.

Inert ingredients in food-use formulations must be cleared for such use under 40 CFR 180-1001. The inert ingredients in the end use bifenox products are exempt according to 40 CFR 180.1001(c) and (d).

2. Acute Toxicity Limits

The Agency will consider registration of any end use bifenox product for nondomestic use in the following categories:

	I	II	III	IV
Acute oral toxicity	yes	yes	yes	yes
Acute dermal toxicity	yes	yes	yes	yes
Acute inhalation toxicity	yes	yes	yes	yes
Primary eye irritation	yes	yes	yes	yes
Primary dermal irritation	yes	yes	yes	yes

3. Use Patterns and Applications Methods

To be registered under this Standard, end use products of bifenox must be labeled as herbicides for the following uses:

food uses	non-food uses
corn	forest nursery seedbeds
rice	
sorghum	
soybeans	
small grains (oats, barley, wheat)	

The Agency finds that it must limit application rates not to exceed current levels because of a lack of adequate data needed to complete a hazard assessment. This is an interim measure which may need to be reassessed following the receipt of required data.

F. REQUIRED LABELING

All manufacturing-use and end-use bifenox products must bear appropriate labeling as specified in 40 CFR 162.10. The guidance package for this Standard contains specific information regarding label requirements.

1. Manufacturing-Use Products

a. Use Pattern Statements

All manufacturing-use bifenox products must list on the label the intended end-uses of formulated products produced from the manufacturing-use product. In accordance with data to be submitted or cited, all manufacturing-use bifenox labels must bear the following statement:

> "For Formulation into End-Use Herbicide Products Intended Only for Terrestrial and Aquatic Use"

b. Precautionary Statements

There are no unique precautionary statements which must appear on the bifenox label. The guidance package provides an updated list of all standard precautionary statements which must appear for this type of product. The Agency may, after review of data to be submitted under this Standard, impose additional label requirements.

2. End Use Bifenox Products

There are no unique precautionary statements which must appear on the bifenox label. The guidance package provides an updated list of all standard precautionary statements which must appear for this type of product.

The Agency may, after review of data to be submitted under this Standard, impose additional label requirements.

G. TOLERANCE REASSESSMENT

A tolerance of 0.05 ppm has been established in the United States for residues of bifenox (40 CFR 180.351) in or on the following raw agricultural commodities:

Barley (grain, straw)
Corn (field, fodder, forage)
Oats (grain, straw)
Rice (grain,straw)
Sorghum (forage, grain)
Soybeans (forage, hay)
Wheat (grain, straw)

Residue studies conducted on the above commodities show that bifenox residues do not exceed the established pesticide tolerance of 0.05 ppm. No evidence of bifenox residues were found in animal feed items at the practical sensitivity (0.05ppm) of the method. Thus, there is no reasonable expectation of residues in meat, milk, or poultry and eggs.

Based on the established tolerances, the theoretical maximum residue concentration in the diet of bifenox is calculated to be 0.0099 mg/day. In the absence of a toxicology data base, the Agency is unable to set a No Observable Effect Level (NOEL) for bifenox.

No recommendation for maximum residue limits has been made for this chemical by the Codex Alimentarius Commission.

Tolerances have not been established in Mexico for residues of bifenox. Negligible tolerances have been established in Canada at 0.1 ppm in barley, oats and wheat for residues of bifenox.

The U.S. tolerance is a negligible tolerance and could be made consistent with the Canadian tolerance; i.e. 0.1 ppm for the grain crop grouping as defined under Title 40, section 180.34(F), which states in part:

> "It may be possible to make a reliable estimate of negligible residues of pesticide chemicals to be expected on each commodity in a designated grouping on the basis of data on a representative number of commodities listed in the following designated groups."

The commodities listed for grain crops include any crop belonging to the family Graminae that produces mature seeds that are used for food or feed, barley, buckwheat, corn (field corn, sweet corn, and popcorn), millet, milo, oats, rice, rye, sorghums (grain), and wheat.

When the Agency establishes "crop group" tolerances, bifenox would appear to be an ideal candidate for a grain crop tolerance.

Upon receipt of the required toxicology data, tolerances may be reassessed.

III. DATA REQUIREMENTS AND DATA GAPS

A. MANUFACTURING-USE BIFENOX

The toxicology data available to the Agency on bifenox were generated by Industrial Bio-Test Laboratories (IBT). These studies currently are being reviewed by the Canadian government under the EPA Laboratory Audit Program. Under the Registration Standard Program, Agency's policy provides that IBT studies which have not yet been reviewed are considered administratively invalid and will not be included in the Registration Standard. Thus, data requirements identified in the Tables which follow do not reflect company submitted studies which were conducted by IBT. In addition, science chapters do not reflect information contained in IBT studies that have not yet been validated.

Table 1, entitled Bifenox Generic Data Requirements, includes those data that pertain to the properties or effects of bifenox as an active ingredient. Thus, these data are relevant to an evaluation of the risks and benefits of all products containing bifenox. Providing data to fulfill indicated gaps is the primary responsibility of the manufacturing-use product registrant(s). Registrants of end-use products which are not exempted by FIFRA Section 3(c)(2)(D) are also responsible for the submission of these data. Applicants for the registration or reregistration of manufacturing-use bifenox products must acknowledge reliance on existing data which fulfill indicated data requirements under FIFRA 3(c)(1)(D). These data are listed under the column entitled Bibliographic Citation in this table.

Table 2, entitled Bifenox Product-Specific Data Requirements for Manufacturing-Use Products, includes those data that relate only to the properties or effects of a product with a specific composition. Thus, these data are required of each product to characterize the product's particular composition and physical/chemical properties, and acute toxicity. Providing data to fulfill these data requirements for a particular product is the responsibility of each applicant for the registration or reregistration of a manufacturing-use bifenox product. If the Agency has in its possession product-specific data which fulfill a data requirement for a particular product, this is indicated in the guidance package accompanying this Standard.

Applicants for the registration of new manufacturing-use bifenox products must submit all required product specific data or establish that the proposed product is substantially similar to another product for which the Agency has received acceptable product specific data.

If the Agency has determined that one or more existing manufacturing-use bifenox products are substantially similar, then this, too, is indicated. Product specific data need not be acknowledged under FIFRA 3(c)(1)(D) unless the Agency or registrant has established that a product is substantially similar to another product for which the Agency has received acceptable product specific data. If this should occur, the registrant(s) of the former product(s) is required to acknowledge reliance on these data.

B. END USE PRODUCTS OF BIFENOX

Registrants of end-use bifenox products not exempted by FIFRA Section 3(c)(2)(D) are responsible for the submission of "generic" data described in Tables 1 and 2 of this Chapter, in addition to the product specific data listed in Table 3.

Registrants of all end-use bifenox products are advised that if data are not generated to fulfill generic data requirements for the manufacturing-use product(s), these registrations will be suspended. If continued availability of the manufacturing-use product is desired, this data must be supplied.

Table 3, entitled Bifenox Product-Specific Data Requirements for End-Use Products, includes those data that relate only to the properties or effects of an end-use product with a specific composition.

Table 1
Bifenox Product-Chemistry (See Chapter IV)
Generic Data Requirements

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard
163.61-8(1)	Color	Yes	Technical Grade	All	Mobil MRID #00003518	No
163.61-8(2)	Odor	Yes	Technical Grade	All	Mobil MRID #00003518	No
163.61-8(3)	Melting Point	Yes	Technical Grade	All	Mobil MRID #00003518	No
163.61-8(4)	Solubility	Yes	Technical Grade	Partial[1]	Mobil MRID #00003518	Yes/8 mos.
163.61-8(5)	Stability	Yes	Technical Grade	All	Mobil MRID #0003518	No
163.61-8(6)	Octanol/water Partition coefficent	Yes	Technical Grade	No		Yes/8 mos.
163.61-8(7)	Physical State	Yes	Technical Grade	All	Mobil MRID #0003518	No

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[1] The Proposed Guidelines require that the solubility be reported preferably in g/100 ml of solvent at 20°C or in other terms as ppm. The solubility was reported in percentages without giving the basis on which these percentages were calculated. Therefore, additional data are required.

These data requirements are current as of June, 1981. Refer to guidance package for updated requirements.

Table 1 (cont.)

Bifenox Product-Chemistry (See Chapter IV)
Generic Data Requirements

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard
163.61-8(8)	Density or Specific Gravity	Yes	Technical Grade	No		Yes/8 mos.
163.61-8(9)	Boiling Point	No[1/]				
163.61-8(10)	Vapor Pressure	Yes	Technical Grade	All	Mobil MRID #00003518	No
163.61-8(11)	pH	Yes	Technical Grade	No		Yes/8 mos.

[1/] Not applicable to a solid.

These data requirements are current as of June, 1981. Refer to guidance package for updated requirements.

Table 1 (Cont'd)
Bifenox Environmental Fate (See Chapter V)
Generic Data Requirements[1]

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard
163.62-7(b)	Hydrolysis	Yes	See Footnote 2	Partial[3]	Lee, Metcalf, Hsu 1976 MRID #05002741	Yes/24 mos.
163.62-7(c)	Photodegradation	Yes	See Footnote 2	No		Yes/24 mos.
163.62-8(b)	Aerobic soil metabolism	Yes	See Footnote 2	Partial[4]	Ohyama, Kuwatsuka, 1975 MRID #05005107 Mobil MRID #00003427 Mobil, 1972 #00003428 Mobil, 1976 #00003358	Yes/24 mos.
163.62-8(c)	Anaerobic soil metabolism	No				
163.62-8(d)	Anaerobic aquatic metabolism	Yes	See Footnote 2	No		Yes/24 mos.
163.62-8(e)	Aerobic aquatic metabolism	Yes	See Footnote 2	No		Yes/24 mos.

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[1] Data requirements apply to manufacturing-use and end-use products.

[2] Radio-labelled analytical grade or non-radio-labelled technical.

[3] The formation of transformation products by hydrolysis could not be distinguished from other chemical or biological means because the study was not conducted under controlled laboratory conditions in the dark.

[4] All data specified in section 163.62-8(b) of the Guidelines for aerobic soil metabolism are needed to assess the metabolism of bifenox in soil.

These data requirements are current as of June, 1981. Refer to guidance package for updated requirements.

Table 1 (Cont'd)
Bifenox Environmental Fate (See Chapter V)
Generic Data Requirements

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard
163.62-8(f)	Microbial metabolism					
	(2) effects of microbes on pesticides	Yes[1]		No		Reserved
	(3) effects of pesticides on microbes	Yes[1]		No		Reserved

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[1] The requirement for the submission of these data is currently being reserved pending the review and modification of the testing protocols.

These data requirements are current as of June, 1981. Refer to guidance package for updated requirements.

Table 1 (Cont'd)
Bifenox Environmental Fate (See Chapter V)
Generic Data Requirements

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard
163.62-8(g)	Activated sludge metabolism	Yes[3/]		No		Reserved
163.62-9(b)	Leaching	Yes[4/]	See Footnote 1	Partial[5/]	Leather, Foy MRID #05002738	Yes/24 mos.
163.62-9(c)	Volatility	No				
163.62-9(d)	Adsorption/ desorption	Yes[6/]	See Footnote 1	No		Yes/24 mos.
163.62-9(e)	Water dispersal	Yes	See Footnote 2	No		Yes/24 mos.
163.62-10(b)	Terrestrial field dissipation					
	(1) Field & vegetable crop	Yes[4/]	See Footnote 2	No		Yes/24 mos.
	(2) Tree Fruit & nut crop uses	No				No
	(3) Pasture land uses	No				No
	(4) Domestic outdoor parks, ornamentals and turf uses	No				

1/ Radio-labelled analytical grade or non-radio-labelled technical.

2/ A representative formulated product.

3/ The requirement for the submission of these data is currently being reserved pending the review and modification of the testing protocols.

4/ For terrestrial noncrop uses, orchard crop uses, field-vegetable crop uses, and forestry uses, the mobility of the test substance and its degradates in soil shall be assessed either by soil thin layer caromatography, soil columns, or batca equilibrium (adsorption/ disorption) procedures.

5/ Only one study was used to test pesticide leaching. A minimum of four studies is required according to 163.62-9 of the guidelines. All specified data in 163.62-9(b) are needed to determine the susceptability of bifenox to leaching.

6/ For domestic outdoor uses, greenhouse uses, aquatic uses, and aquatic impact uses, the mobility of the test substance and its degradates in soil shall be assessed only by the batch equilibrium (adsorption/desorption) procedure.

Table 1 (Cont'd)

Bifenox Environmental Fate (See Chapter V)
Generic Data Requirements

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard
	(5) Rights of way, shelterbelts and related uses	No				
163.62-10(c)	Aquatic field dissipation					
	(1) Aquatic food crop uses	Yes	See Footnote 1	Partial[2/]	Mobil, 1973 MRID #00003461	Yes/24 mos.
	(2) Aquatic noncrop uses	No				
	(3) Specialized aquatic uses	No				
163.62-10(d)	Terrestrial/ aquatic (forest) field dissipation	No				
163.62-10(e)	Aquatic impact uses					
	(1) Direct discharge	No				
	(2) Indirect discharge	No				
	(3) Wastewater treatment	No				

1/ Each formulated end-use product.

2/ All data specified in Section 163.62-10(c) of the Guidelines are needed to determine the dissipation rate of bifenox of each formulated end-use product in the aquatic environment.

These data requirements are current as of June, 1981. Refer to guidance

Table 1 (Cont'd)
Bifenox Environmental Fate (See Chapter V)
Generic Data Requirements

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard
163.62-10(f)	Combination and tank mix field dissipation	No 1/				
163.62-10(g)	Long term field dissipation study	Yes 8/	See Footnote 3	No		Reserved
163.62-11(b)	Accumulation in rotational crops	Yes	See Footnote 2	Partial 6/	Leather/Foy, 1977 MRID #05002738	Yes/ 24 mos.
163.62-11(c)	Accumulation in irrigated crops	Yes	See Footnote 3	No		Yes/24 mos.
163.62-11(d)	Fish accumulation	Yes	See Footnote 4	Partial 7/	Lee, Metacalf Hsu, 1975 MRID #05002741	Yes/24 mos.
163.62-11(e)	Special studies accumulation in aquatic noncrop uses	No				
163.62-13	Disposal and storage	Yes 5/		No		Reserved

1/ Not applicable to single active ingredient standard.

2/ Radio-labelled analytical grade (if residues are found, then a field test using a representative formulation).

3/ A representative formulated product.

4/ Radio-labelled analytical grade or non-radio-labelled technical.

5/ The requirement for the submission of these data is currently being reserved pending the review and modification of the testing protocols.

6/ Additional data are needed in greenhouse studies using crops other than oats to determine if bifenox residues will accumulate in rotational crops and additional field data are needed on the accumulation of bifenox in oats.

7/ Additional studies using other recommended species of fish, a flow-through exposure system, more extensive sampling, and a depuration period are needed to properly evaluate the environmental effect of bifenox on fish.

8/ The requirement for submission of these data is reserved pending evaluation of terrestrial and aquatic field data.

Table 1 (Cont'd)

Bifenox Toxicology (See Chapter VI)
Generic Data Requirements

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard
163.81-1	Acute Oral Toxicity	Yes	Technical Grade	No		Yes/8 Mos.
163.81-2	Acute Dermal Toxicity	Yes	Technical Grade	No		Yes/8 Mos.
163.81-3	Acute Inhalation	Yes	Technical Grade	No		Yes/8 Mos.
163.81-4	Primary Eye Irritation	Yes	Technical Grade	No		Yes/8 Mos.
163.81-5	Primary Dermal Irritation	Yes	Technical Grade	No		Yes/8 Mos.
163.81-6	Dermal Sensitization	Yes	Technical Grade	No		Yes/8 Mos.
163.81-7	Acute Neurotoxicity	No[1/]	Technical Grade	No		No

[1/] Acute delayed neurotoxicity data are not required because bifenox is not expected to cause esterase depression nor is it structurally related to a compound that induces neutopathy or delayed neurotoxicity.

These data requirements are current as of June, 1981. Refer to guidance package for updated requirements.

Table 1 (Cont'd)
Bifenox Toxicology (See Chapter VI)
Generic Data Requirements

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard
163.82-1	Subchronic Oral Toxicity	Yes[1/]	Technical Grade			Yes/24 mons.
163.82-2	Subchronic 21-day Dermal Toxicity	Yes[2/]	Technical Grade			Yes/24 mos.
163.82-3	Subchronic 90-day Dermal Toxicity	No	Technical Grade			No
163.82-4	Subchronic Inhalation Toxicity	No[3/]	Technical Grade			No
163.82-5	Subchronic Neurotoxicity	No[4/]	Technical Grade			No

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1/ This test is required for bifenox because its use requires a tolerance.
2/ This test is required for bifenox because its use may result in repeated skin contact.
3/ Acute inhalation data were not available. A subchronic test may be required pending results of an acute inhalation test.
4/ Acute delayed neurotoxicity data are not required because bifenox is not expected to cause esterase depression, nor is it structurally related to a compound that induces neuropathy or delayed neurotoxicity.

These data requirements are current as of June, 1981. Refer to guidance package for updated requirements.

Table 1 (Cont'd)

Bifenox Toxicology (See Chapter VI)
Generic Data Requirements

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard
163.83-1	Chronic Feeding	Yes	Technical Grade	No[1]		Yes
163.83-2	Oncogenicity	Yes	Technical Grade	No[1]		Yes
163.83-3	Teratogenicity	Yes	Technical Grade	No[1]		Yes
163.83-4	Reproduction	Yes	Technical Grade	No[1]		Yes
163.84-2 through 4	Mutagenicity	Yes	Technical Grade	No[1]		Yes
163.85-1	Metabolism	Yes	Technical Grade	No		Yes 24 mos.

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[1] The submitted data are IBT data that are considered invalid for purposes of this standard. The Canadian government is validating IBT data for EPA. Consult with EPA Laboratory Audit Program prior to initiating studies.

These data requirements are current as of June, 1981. Refer to guidance package for updated requirements.

Table 1 (Cont'd)
Bifenox Residue Chemistry (See Chapter VII)
Generic Data Requirements

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard
—	Metabolism in in Plants	Yes	Technical Grade	All	Leather/Foy MRID #05007738 Leather MRID #05002878	No
—	Metabolism in Animals	Yes	Technical Grade	All	See Footnote 1	No
—	Analytical Methods	Yes	Technical Grade	All	See Footnote 2	No
—	Residue Data: Field Corn	Yes	Technical Grade	All	See Footnote 3	No
—	Residue Data: Rice	Yes	Technical Grade	All	See Footnote 3	No
—	Residue Data: Sorghum, Grain and Fodder	Yes	Technical Grade	All	See Footnote 3	No
--	Residue Data: Barley, Oats, and Wheat	Yes	Technical Grade	All	See Footnote 3	No
	Residue Data: Milk, Meat, and Eggs	Yes	Technical Grade	All	MRID #00003478	No
	Storage Stability	Yes	Technical Grade	All	MRID #00003523	No

1/ This requirement is satisfied by the following studies: MRID 05005107, 05002738, 05002879.
2/ This requirement is satisfied by the following studies: MRID 00003522, 05005105, 00003413.
3/ This requirement is satisfied by the following studies: MRID 00003432, 00003478, 00003521, 00003435, 00003536, 00004175, 00003434, 00003433.

These data requirements are current as of June, 1981. Refer to guidance package for updated requirements.

Table 1 (Cont'd)
Bifenox Ecological Effects (See Chapter VIII)
Generic Data Requirements

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard
163.72-1	Fish Acute LC_{50}	Yes	Technical Grade	No[2/]		Yes/8 mos.
163.72-2	Acute Toxicity to Aquatic Invertebrates	Yes	Technical Grade	No[3/]		Yes/8 mos.
163.72-3	Acute Toxicity to Estaurine and Marine Organisms	Yes	Technical Grade	No[4/]		Yes/8 mos.
163.72-4	Embryolarvae and Life-cycle Studies of Fish and Aquatic Invertebrates	No[1/]				Reserved
163.72-5	Aquatic Organism Toxicity and Residue Studies	No[1/]				Reserved
163.72-6	Simulated or Actual Field Testing for Aquatic Organisms	No[1/]				Reserved

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[1/] The requirement for submission of these data is currently reserved pending the results of the following tests: Fish Acute LC_{50}, Acute Toxicity to Aquatic Invertebrates.

[2/] Six studies (contained in 3 references) were evaluated and reviewed and found to be unacceptable for use in establishing the acute toxicity of bifenox to freshwater fish (warmwater or coldwater).

[3/] The guideline requirements for an LD_{50} on aquatic invertebrates with technical bifenox have not been satisfied.

[4/] No studies were submitted on technical bifenox. The guideline requirements for an LC_{50} on estaurine and marine organisms have not been satisfied.

These data requirements are current as of June, 1981. Refer to guidance package for updated requirements.

Table 1 (Cont'd)

Bifenox Ecological Effects (See Chapter VIII)
Generic Data Requirements

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard
163.71-1	Avian Single-Dose Oral LD_{50}	Yes	Technical Grade	No[1]		Yes/8 mos.
163.71-2	Avian Dietary LC_{50}	Yes	Technical Grade	No[1]		Yes/8 mos.
163.71-3	Mammalian Acute Toxicity	No				No
163.71-4	Avian Reproduction	No				No
163.71-5	Simulated and Actual Field Testing for Mammals and Birds	No				No

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[1] The submitted data are IBT data and are considered invalid for purposes of this standard. The Canadian government is validating IBT data for EPA. Consult with EPA Laboratory Audit Program prior to initiating studies.

These data requirements are current as of June, 1981. Refer to guidance package for updated requirements.

Table 1 (Cont'd)

Bifenox Ecological Effects (See Chapter VIII)
Generic Data Requirements for Bifenox by Composition Characteristics

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard
163.122-1	Seed Germination	Yes		No		Yes1/
163.122-1	Vegetative Vigor	Yes		Yes	See Footnote 2	No
163.122-2	Aquatic Macrophytes	Yes		No		Yes1/
163.122-2	Algae	Yes		No		Yes1/

1/ Data requirements must be fulfilled within 2 years using technical bifenox.

2/ This requirement is satisfied by the following studies in aggregate: 00003364, 00003379, 00003381, 00003384, 00003387, 00003402, 00003404, 00003408, 00003410, 00003415, 00003450, 00003453, 00003462, 00003463, 00003466, 00003471, 00003472, 00003475, 00003482, 00003483, 00003484, 00003494, 00003499, 00003508, 00003520, 00003527, 00003533, 00003544, 00003546, 00003547, 00003550, 00003551, 00003553, 00003555, 00003558, 00003561, 00003571, 00004176, 00004181, 00004183, 00004185, 00004186, 00004189, 00004192, 00004194, 00004202, 00004986, 00004988, 00004989, and 05004454.

These data requirements are current as of June, 1981. Refer to guidance package for updated requirements.

Table 2
Product Chemistry (See Chapter IV)
Bifenox Product-Specific Data Requirements for Manufacturing-use Products

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard
163.61-3	Product Identity and Disclosure of Ingredients	Yes*	MUP	All	Mobil MRID #00003518	No
163.61-4	Description of Manufacturing Process	Yes*	MUP	All	Mobil MRID #00003518	No
163.61-5	Discussion of Formation of Unint. Ingredients	Yes*	MUP	All	Footnote[2]	No
163.61-6	Declaration and Certification of Ingredient Limits	Yes*	MUP	All	Footnote[2]	No
163.61-7	Product Analytical Methods and Data	Yes*	MUP	Partial[1]	Melnizek, 1972 MRID #00003522	Yes/8 mos.
163.61-8(7)	Physical State	Yes	MUP	All	Mobil MRID #00003518	No
163.61-8(8)	Density or Specific Gravity	Yes	MUP	No		Yes/8 mos.
163.61-8(9)	Boiling Point	No				

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* These data requirements for the manufacturing-use product are satisfied by the requirements for the technical. Refer to Chapter IV Product Chemistry.

1/ Analytical methodology are needed to detect and measure any ingredient or impurity in the intentionally-added inert ingredients.

2/ The data was obtained from the Confidential Statement of Formula.

These data requirements are current as of June, 1981. Refer to guidance

Table 2 (Cont'd)

Product Chemistry (See Chapter IV)
Bifenox Product-Specific Data Requirements for Manufacturing-use Products

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard
163.61-8(11)	pH	Yes	MUP	No		Yes/8 mos.
163.61-8(12)	Storage Stability	Yes	MUP	All	Mobil MRID #00003523	No
163.61-8(13)	Flammability	Yes	MUP	No		Yes/8 mos.
163.61-8(14)	Oxidizing or Reducing Action	Yes	MUP	No		Yes/8 mos.
163.61-8(15)	Explosiveness	Yes	MUP	No		Yes/8 mos.
163.61-8(16)	Miscibility	Yes[1/]	MUP			No
163.61-8(17)	Viscosity	Yes[2/]	MUP			No
163.61-8(18)	Corrosion Characteristics	Yes	MUP	No		Yes/8 mos.

[1/] EC liquids only.
[2/] Liquids only.

These data requirements are current as of June, 1981. Refer to guidance package for updated requirements.

Table 2 (Cont'd)

Bifenox Toxicology (See Chapter VI)
Product-Specific Data Requirements for Manufacturing-Use Products

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard
163.81-1	Acute Oral Toxicity	Yes*	MUP	No		Yes/8 mos.
163.81-2	Acute Dermal Toxicity	Yes*	MUP	No		Yes/8 mos.
163.81-3	Acute Inhalation Toxicity	Yes*	MUP	No		Yes/8 mos.
163.81-4	Primary Eye Irritation	Yes*	MUP	No		Yes/8 mos.
163.81-5	Primary Dermal Irritation	Yes *	MUP	No		Yes/8 mos.
163.81-6	Dermal Sensitization	Yes*	MUP	No		Yes/8 mos.

* The technical and the manufacturing-use have been determined to be the same. These requirements may be filled by data required in Table 1 entitled "Bifenox Toxicology Generic Data Requirements."

These data requirements are current as of June, 1981. Refer to guidance package for updated requirements.

Table 3
Product Chemistry (See Chapter IV)
Product-Specific Data Requirements for End-Use Products

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard
163.61-3	Product Identity and Disclosure of Ingredients	Yes	Each product	All	Mobil MRID #00003519[2]	No
163.61-4	Description of Manufacturing Process	Yes	Each product	All	Mobil MRID #00003519[2]	No
163.61-5	Discussion of Formation of Unint. Ingredients	Yes	Each product	All	Mobil MRID #00003519[2]	No
163.61-6	Declaration and Certification of Ingredient Limits	Yes	Each product	No		Yes/8 mos.
163.61-7	Product Analytical Method and Data	Yes	Each product	No		Yes/8 mos.
163.61-8(1)	Color	Yes	Each product	No		Yes/8 mos.
163.61-8(2)	Odor	Yes	Each product	No		Yes/8 mos.
163.61-8(7)	Physical State	Yes	Each product	All	Mobil MRID #00003523	No
163.61-8(8)	Density or Specific Gravity	Yes	Each product	Partial[1]	Mobil MRID 00003523	Yes/8 mos.
163.61-8(9)	Boiling Point	No				

1/ Data requirements have been satified for the EC, 75% wettable powder and flowable. Data are required for the 80% wettable powder.
2/ Some of the data was obtained from the Confidential Statement of Ingredients.

These data requirements are current as of June, 1981. Refer to guidance

Table 3 (Cont'd)

Bifenox Product Chemistry (See Chapter IV)
Product-Specific Data Requirements for End-Use Products

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard
163.61-8(10)	Vapor Pressure	Yes	Each product	All	See Footnote 4	No
163.61-8(11)	pH	Yes	Each product[1]	No	See Footnote 4	Yes/8 mos.
163.61-8(12)	Storage Stability	Yes	Each product	All	MRID 00003523	No
163.61-8(13)	Flammability	Yes	Each product[2]	No	MRID 00003523	Yes/8 mos.
163.61-8(14)	Oxidizing or Reducing Action	Yes	Each product	No		Yes/8 mos.
163.61-8(15)	Explosiveness	Yes	Each product	No	•	Yes/8 mos.
163.61-8(16)	Miscibility	Yes	Each product	Partial*	See Footnote[4]	Yes/8 mos.
163.61-8(17)	Viscosity	Yes	Each product[3]	No	See Footnote 4	Yes/8 mos.
163.61-8(18)	Corrosion Characteristics	Yes	Each product	Partial**	See Footnote 4	Yes/8 mos.

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* Data are require on emulsifiable liquids only. Data is needed on the EC.

** Data requirements have been satisfied for the EC. Data are required on the 4 flowable and WP.

[1] Data requirements have been satisfied for the EC and flowable. Data are required on the 75 and 80% wettable powder.

[2] Data requirements have been satisfied for the EC and WP. Additional data are required on the 4 flowable.

[3] Data requirements have been satisfied for the EC and WP. Additional data are required on the 4 flowable.

[4] The data was obtained from the Confidential Statement of Formula.

These data requirements are current as of June, 1981. Refer to guidance package for updated requirements.

Table 3 (Cont'd)

Bifenox Toxicology (See Chapter VI)
Product-Specific Data Requirements for End-Use Products

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard
1. Wettable Powder (80%)						
163.81-1	Acute Oral Toxicity	Yes	Each Product[1]	No		Yes/8 mos.
163.81-2	Acute Dermal Toxicity	Yes	Each Product[1]	No		Yes/8 mos.
163.81-3	Acute Inhalation Toxicity	Yes	Each Product[1]	No		Yes/8 mos.
163.81-4	Primary Eye Irritation	Yes	Each Product[1]	No		Yes/8 mos.
163.81-5	Primary Dermal Irritation	Yes	Each Product[1]	No		Yes/8 mos.
163.81-6	Dermal Sensitization	Yes	Each Product[1]	No		Yes/8 mos.

[1] Each product or substantially similar product.

These data requirements are current as of June, 1981. Refer to guidance package for updated requirements.

Table 3 (Cont'd)

Bifenox Toxicology (See Chapter VI)
Product-Specific Data Requirements for End-Use Products

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard
2. Emulsifiable Concentrate (21%)						
163.81-1	Acute Oral Toxicity	Yes	Each product[1]	No		Yes/8 mos.
163.81-2	Acute Dermal Toxicity	Yes	Each product[1]	No		Yes/8 mos.
163.81-3	Acute Inhalation Toxicity	Yes	Each product[1]	No		Yes/8 mos.
163.81-4	Primary Eye Irritation	Yes	Each product[1]	No		Yes/8 mos.
163.81-5	Primary Dermal Irritation	Yes	Each product[1]	No		Yes/8 mos.
163.81-6	Dermal Sensitization	Yes	Each product[1]	No		Yes/8 mos.

1/ Each product or substantially similar product.

These data requirements are current as of June, 1981. Refer to guidance package for updated requirements.

Table 3 (Cont'd)

Bifenox Toxicology (See Chapter VI)
Product-Specific Data Requirements for End-Use Products

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard
3. Flowable (40%)						
163.81-1	Acute Oral Toxicity	Yes	Each Product[1/]	No		Yes/8 mos.
163.81-2	Acute Dermal Toxicity	Yes	Each Product[1/]	No		Yes/8 mos.
163.81-3	Acute Inhalation Toxicity	Yes	Each Product[1/]	No		Yes/8 mos.
163.81-4	Primary Eye Irritation	Yes	Each Product[1/]	No		Yes/8 mos.
163.81-5	Primary Dermal Irritation	Yes	Each Product[1/]	No		Yes/8 mos.
163.81-6	Dermal Sensitization	Yes	Each Product[1/]	No		Yes/8 mos.

[1/] Each product or substantially similar product.

These data requirements are current as of June, 1981. Refer to guidance package for updated requirements.

Table 3 (Cont'd)
Ecological Effects (See Chapter VIII) Product-Specific Data Requirements for End-use Products

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard
1. Wettable Powder (80%)						
163.72-1	Fish Acute LC_{50}	Yes	Each product	No[1]		Yes/8 mos.
163.72-2	Acute Toxicity to Aquatic Invertebrates	Yes	Each product	No[1]		Yes/8 mos.
163.72-3	Acute Toxicity to Estaurine and Marine Organisms	Yes	Each product	No		Yes/8 mos.
2. Emulsifiable Concentrate (21%)						
163.72-1	Fish Acute LC_{50}	Yes	Each product	No[1]		Yes/8 mos.
163.72-2	Acute Toxicity to Aquatic Invertebrates	Yes	Each product	No		Yes/8 mos.
163.72-3	Acute Toxicity to Estaurine and Marine Organisms	Yes	Each product	No[1]		Yes/8 mos.
3. Flowable (40%)						
163.72-1	Fish Acute LC_{50}	Yes	Each product	No[2]		Yes/8 mos.
163.72-2	Acute Toxicity to Aquatic Invertebrates	Yes	Each product	Yes	LeBlanc , 1976 MRID #00003366	No
163.72-3	Acute Toxicity to Estaurine and Marine Organisms	Yes	Each product	Partial[3]	Hollister, 1976 MRID 00003367	Yes/8 mos.

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[1] The direct application of bifenox to water (rice use) poses a potential hazard to aquatic organisms. These data are needed to assess this potential hazard.

[2] Additional acute toxicity data are needed on the 40% flowable product.

[3] The 96-hour acute toxicity on pink shrimp was submitted (LC_{50} = 2.6 ppm. However, an LC_{50} study on an estuarine fish, and a 48-hour oyster embryolarva study are still required.

These data requirements are current as of June, 1981. Refer to guidance package for updated requirements.

IV. PRODUCT CHEMISTRY

A. INTRODUCTION

FIFRA 3(c)(2)(A) requires the Agency to establish guidelines for registering pesticides in the United States. The Agency requires registrants to provide quantitative data on all unintentional ingredients which are equal to or greater than 0.1% of the product by weight.

To establish the composition of products proposed for registration, the Agency requires data and information not only on the manufacturing and formulation processes, but also a discussion on the formation of manufacturing impurities and other product ingredients, intentional and unintentional. Further, to assure that the composition of the product as marketed will not vary from the composition evaluated at the time of registration, applicants are required to submit a statement certifying upper and lower composition limits for the added ingredients and upper limits only for some unintentional ingredients. Guidelines Subpart D (43 FR 29696) suggests specific precision limits for ingredients based on the percentage of ingredient and the standard deviation of the analytical method.

In addition to the data on product composition, the Agency also requires data to establish the physical and chemical properties of both the pesticide active ingredient and its formulations. For example, data are needed concerning the identity and physical state of the active ingredient (e.g., melting point data, ambient vapor pressure and solubility). Data are also required on the properties of the formulated product to establish labeling cautions (e.g., flammability, corrosivity and storage stability). The agency uses these data to characterize each pesticide and to determine its environmental and health hazards.

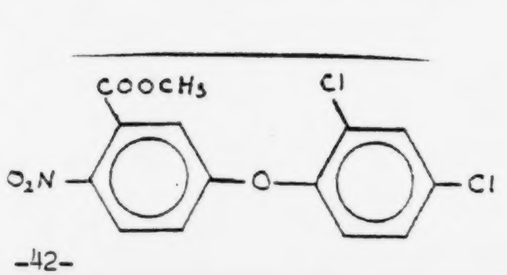
B. PRODUCT CHEMISTRY - MANUFACTURING-USE BIFENOX

Product Chemistry Profile

1. Chemical Identity

Bifenox is the accepted common name for methyl 5-(2,4-dichlorophenoxy)-2-nitrobenzoate. It is also known by the trade name Modown^{R}. Other chemical names include: benzoic acid, 5-(2,4-dichlorophenoxy)-2-nitro-, methyl ester (8, 9 CI), and 2,4-Dichlorophenyl 3'-methoxycarbonyl-4'-nitrophenyl ether.

The chemical structure is:



The chemical formula for bifenox is $C_{14}H_9Cl_2NO_5$ and the molecular weight is 342.12. The Chemicial Abstracts Registry (CAS) number for bifenox is 42576-02-3 (formerly 12680-11-4), and the EPA Shaughnessy Number is 104301.

The common name bifenox will be used routinely in this registration standard in lieu of trade and other names.

2. Manufacturing Process

Bifenox can be made by the reaction of potassium 2,4-dichlorophenolate with methyl 5-chloro-2-nitrobenzoate (Martin and Worthing, MRID 05000993). Chemicals of the type of bifenox "are readily prepared by the Ullman (sic) ether synthesis reaction between the alkali metal (Na,K) salt of a halophenol and a 5-halo (Cl or Br)-2-nitrobenzoic acid or an ester, amide, or salt thereof. The 5-halo-2-nitrobenzoic acid is readily prepared by nitrating an m-halo-toluene followed by oxidation of the methyl group by well known procedures" (Sittig, 1977). The company has submitted data on its manufacturing process. These data are included in Confidential Appendix A.

The Farms Chemical Handbook (1980) lists the Mobil Chemical Company as the only basic producer of bifenox in the United States.

3. Formation of Unintentional Impurities

Data identifying impurities in the technical product have been submitted but cannot be discussed because of its confidentiality. These data are found in Confidential Appendix A.

4. Active Ingredient Limits in Pesticide Products

Manufacturing-Use Bifenox

The active ingredient limits for technical bifenox contains a minimum of 96% of the active ingredient, methyl 5-(2,4-dichlorophenoxy)-2-nitrobenzoate. Depending upon the manufacturing process, up to 4% related impurities can be expected. Because of its confidentiality, submitted data identifying impurities in the technical product and a discussion of the specific procedures, equipment and manufacturing conditions required for the commercial production of bifenox will not be discussed or included in this Standard.

End Use Products

The intentionally added inert ingredients of the end use products are exempt from the requirements of a tolerance under 40 CFR 180.1001 (c) and (d). These data are to be found in Confidential Appendix B.

5. Product Analytical Method

The analytical method (Mobil Chemical Method 69-72) is considered an adequate method for bifenox and is in compliance with section 163.61-7(a)(3) of the Proposed Guidelines. However, there are no methods for the unintentional ingredients.

C. PHYSICAL AND CHEMICAL PROPERTIES

1. Available data from the open literature and registrant submissions on the physical/chemical properties of technical bifenox are:

Color	Pale yellow to tan	(00003518)
Odor	Faint	(00003518)
Melting point	84-86° C	(00003518)
Physical state	Crystalline solid	(00003518)
Vapor pressure	2.4×10^{-6} mm Hg at 30° C	(00003518)
Stability	Heat stable to 175° C, loses weight to 285° C, total decomposition occurs above 290° C	(00003518)
Solubility		(00003518)

Solvent	Approximate % (at 20° C)
Corn Oil	3-4
Methanol	2
Xylene	30
Methyl Isoamyl Ketone	25
Methyl Chloride	50
Pine Oil	2-3
Chlorobenzene	35-40
Ethylene Dichloride	40
Methyl Methacrylate	35-40
Kerosene, other aliphatics	<1
Mesityl Oxide	40-50
Isophorone	20-40
Cyclohexanone	40-50
Diacetone alcohol	16-20
1,4-Dioxane	10-15
Water	0.36 ppm

2. The following physical/chemical properties for manufacturing-use bifenox are:

Physical state ---------- Crystalline solid (00003518)
Storage stability ------- Technical bifenox stored at 20-30° C for 52 weeks showed no loss of active ingredient (00003523)

3. Available data on the physical/chemical properties on the end-use products are:

80% Wettable Powder
Physical state --------- Solid (00003523)

75% Wettable Powder
Physical state --------- Solid (00003523)
Density ---------------- 24 lbs./cu.ft.

4 Flowable
Physical state --------- Liquid (00003523)
Density ---------------- 10 lbs./gal.
pH --------------------- 7
Flash point ------------ greater than 200

Emulsifiable Concentrate
Physical state --------- Liquid (00003523)
Density ---------------- 9.63 lbs./gal.
Flammability ----------- 94°F (TOC)
Viscosity -------------- 2.03 cp at 25° C
Storage stability ------ The formulation is stable for 12 weeks at 50° C (00003523)
Corrosion Characteristics -------------- Not corrosive to stainless steel or aluminum, but corrosive to the extent of 0.8 mils/year to carbon steel, and 0.6 mils/year to brass

D. SUMMARY OF DATA GAPS

1. Technical Bifenox

The data gaps for technical bifenox are solubility, octanol/water partition coefficient, density or specific gravity and pH.

2. Manufacturing-Use Bifenox

The data gaps for manufacturing-use bifenox are product analytical methods, density or specific gravity, pH, flammability, oxidizing or reducing action, explosiveness, and corrosion characteristics.

3. End Use Products

The data gaps for the end use products are color, odor, density or specific gravity (80 WP only), pH (75 and 80% WP), flammability (4F), oxidizing or reducing action, explosiveness, miscibility (EC only), viscosity (4F) and corrosion characteristics (4F, WP).

In addition, the following will be required for each product: a description of analytical methods for the determination of each identified impurity associated with the technical product; declaration and certification of the upper and lower limits for each active ingredient and intentionally added inert ingredients, and the upper limit of each impurity, reaction and degradation products based on representative samples.

V. ENVIRONMENTAL FATE

A. USE PROFILE

Bifenox is a selective herbicide used in preemergence or postemergence treatments to control many annual broadleaf and certain grass weeds. Registered use sites include soybeans, rice, grain sorghum, field corn, wheat, and forest tree nursery seedbeds.

Bifenox apparently acts by inhibition of photosynthesis or plant respiration. At recommended rates, it is herbicidally active for 6 to 8 weeks in the soil. All formulations are applied in a water carrier without additional sufactants at volumes of 10 to 50 gallons per acre, depending on crop, target weeds, and method of application.

Principal target weeds in rice fields include annual sedge, barnyardgrass, dayflower, ducksalad, redstem, hemp sesbania, sprangletop, and water hyssop. Target weeds in other sites include jimsonweed, lambsquarters, pigweed, smartweed, velvetleaf, morningglory, and teaweed. Bifenox is seldom used for control of hard-to-kill perennial or woody weeds.

There are currently five bifenox formulations, including the technical product. All are single active ingredient formulations. They include two wettable powders containing 75% and 80% active ingredient, a 40% flowable concentrate, and a 21% emulsifiable concentrate. Currently, the most frequently used products are the 80% wettable powder and the 40% flowable concentrate.

More than one-half of current bifenox production is used on soybean, mostly in the Midwestern states. Treatments are either broadcast or applied in bands by ground rig boom sprayers. Bifenox is applied to soybeans mostly as a preemergence treatment, although some preplant treatments are made. Tank mixes with the herbicides alachlor or trifluralin are frequently used.

About 25% to 30% of bifenox production is used for treatment of rice in the South. Both preemergence and postemergence treatments are usually applied by air, although preemergence treatments are occasionally broadcast by ground rig booms. Postemergence treatments are usually tank-mixed with the herbicide propanil, while preemergence treatment is done with bifenox alone.

A small portion of bifenox production is used on field corn and grain sorghum in the Midwest. It is applied to these sites as a preemergence broadcast treatment by ground rig booms. Bifenox may be tank-mixed with the herbicide propachlor for use on sorghum or with the herbicide alachlor for use on corn.

About 2% of bifenox production is used to control weeds in forest tree nursery seedbeds. Principal use areas are conifer plantations in the South and West. Bifenox is applied postemergence by ground rig boom sprayers to young conifer seedlings.

Bifenox, though registered for use on wheat, is not currently used on that crop. According to label instructions, bifenox should be applied as a postemergence broadcast treatment to wheat having from 2 to 4 leaves. Either aerial or ground application may be used.

Additional information about bifenox application on its registered use-sites is contained in Table 1.

B. ENVIRONMENTAL FATE - MANUFACTURING-USE BIFENOX

1. Environmental Fate Summary

Bifenox is hydrolyzed under acidic (pH 4.7) conditions to 5-(2',4'-dichlorophenoxy)-2-nitrobenzoic acid and methyl-5-(2',4'-dichlorophenoxy)anthranilate. Ten potential degradation products were identified that may be contaminants in the starting material, or the result of hydrolysis or photolysis. The products are:

3-Carboxymethyl-4-nitrophenol
3'-Hydroxy-4'-nitro-2,4-dichloro-diphenyl ether
3'-Carboxymethyl-4'-nitro-2,4-dichloro-6-hydroxy-diphenyl ether
3'-Carboxymethyl-4'-hydroxy-2,4-dichloro-diphenyl ether
3'-Carboxymethyl-4'-amino-2,4-dichloro-diphenyl ether
2,4-Dichlorophenol
p-Nitrophenol
3'-Hydroxy-4'-nitro-2-hydroxy-4-chloro-diphenyl ether
3'-Hydroxy-4'-amino-2,4-dihydroxy-diphenyl ether
Nitrofen
(Mobil 1976, MRID 00003543)

Laboratory data indicate that bifenox had a half-life in Anjyo (mineral soil, Kaolin), Tochigi (volcanic ash soil, allophane), and Nagano (mineral soil montmorillonite) soils of 2-4 days under flooded conditions and a half-life of 6 days under aerobic conditions. (Ohyama, Kuwatsuka, 1975, MRID 05005107)

TABLE 1 - Registered Application Rates of Bifenox

Site	Formulation	Application Method	Application rate[1] (lb. or oz. a.i.)
Soybeans	WP F EC*	Preplant or preemergence broadcast, band, or incorporate	1.2-2.0 lbs. A.I./A
Rice	WP F EC	Preemergence or Postemergence Broadcast	2.0-3.0 lbs. A.I./A[2/3]
Grain Sorghum	WP F	Preemergence Broadcast	1.5-2.0 lbs. A.I./A
Forest tree nursery seedbeds	WP F	Preemergence or	3.0 lbs. A.I./A
	EC	Postemergence after seedlings are 4 wks. old	3.0 lbs. A.I./A
Field Corn*	WP F	Preemergence broadcast	1.6-2.0 lbs. A.I./A
Wheat*	EC	Postemergence Broadcast	0.7-1.0 lb. A.I./A[2/3]

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[1] In pounds of active ingredient per acre.

[2] Aerial

[3] Ground

*Not currently marketed for this site in the United States.

In sandy loam and loam soils the half-life of bifenox was 3-14 days. At 6 weeks after treatment, 0.06-0.11 ppm (4-11% of the chemical applied) remained in the sandy loam soils and 0.12-0.21 ppm (11-16% of the chemical aplied) remained in the loam soil. A metabolite [methyl-5-(2,4-dichlorophenoxy) anthranilate] was found in the sandy loam soil at a concentration of 0.12 ppm. These data indicate that bifenox will not present a persistence problem in soil; however, without field data, the true rate of bifenox soil dissipation cannot be determined (Mobil 1972, MRID 00003427, 28; 1978, MRID 00003358).

Data from a nitrification study indicate that bifenox at 31 ppm inhibits nitrification in clay soils for at least 60 days. This may be beneficial in rice fields since rice plants take up NH_4 instead of NO_3. However, 31 ppm is far in excess of the maximum recommended application rate of 1.5 ppm.

A sludge study shows that bifenox is degraded in sewage sludge with approximately two-thirds of the bifenox present in the effluent at zero time degrading in 4 hours (pseudo-first-order rate constant -0.26/hour). (Greer, 1978, MRID 05020066).

A study using a clay loam soil indicated that bifenox and two transformation products 5-(2',4'-dichlorophenoxy)-2-nitrobenzoic acid (a hydrolysis product) and 2,'4'-dichlorophenyl-4-nitrophenyl ether (nitrofen) will leach in soil to a depth of 40 centimeters. However, since the soil was eluted with the equivalent of 332 acre-inches of water, firm conclusions cannot be drawn from the data. (Leather and Foy, 1977, MRID #05002738)

Preliminary data from an aquatic field dissipation study conducted in a rice field treated with 2 or 4 lb/A show that bifenox residue levels decreased from 0.007 and 0.13 ppm, respectively, on the date the field was flooded (18 days after treatment) to nondetectable levels of less than 0.005 ppm at 7 days after flooding (25 days after treatment).

Mosquito fish placed in a model ecosystem 30 days after treatment with bifenox accumulated to 0.024 ppm of bifenox (accumulation factor 50) over a 3-day period. (Lee et at., 1976, MRID 05002741)

Bifenox was applied alone and in combination with alachlor, propanil, and propachlor to sandy loam and loam soils. When bifenox was applied alone, 79-96% of the compound dissipated from the sandy loam and loam soils within 6 weeks. Similar results (73-95% dissipation) were observed when bifenox was applied in combination with alachlor, propachlor, or propanil. Thus, the dissipation rate of bifenox in the environment is not expected to change when it is applied in combination with these compounds. (Mobil MRID 00003327, 3358).

Bifenox residues will accumulate in greenhouse-grown oats. Residues of [14C] bifenox in oats 310 days after treatment included 5-(2',4'-dichlorophenoxy)-2-nitrobenzoic acid, nitrofen, and 5-(2',4'-dichlorophenoxy)anthranilic acid. (Leather & Foy, 1977, MRID #05002738)

Although the data are insufficient to form a comprehensive profile of the fate of bifenox in the environment, it can be concluded that bifenox should not present a persistence problem in soil when used alone or in combination with alachlor, propachlor, propanil. The dissipation of bifenox in soil appears to be through hydrolysis to 5-(2',4'-dichlorophenoxy)-2-nitrobenzoic acid and methyl-5-(2',4'-dichlorophenoxy) anthranilate. However, a transformation product (2,4-dichlorophenyl-4-nitrophenyl ether, the herbicide nitrofen, appears to be a microbial degradation product of bifenox (based on the structural differences between nitrofen and bifenox). Therefore, microbial degradation must still be considered as a possible degradation pathway.

The impact of bifenox on the aquatic environment cannot be determined because the rate of hydrolysis is not known. In addition, the structures of the two hydrolysis products are similar to bifenox, which suggests that they may have similar influences on the environment.

C. EXPOSURE PROFILE

1. All Formulations

The greatest potential for exposure to bifenox occurs during mixing, loading, and spraying operations, but no data are available to estimate the degree of such exposure. Aerial applications may potentially expose humans, livestock and wildlife outside the application site via spray drift. A potential exposure to wildlife exists because of bifenox use on grains and to aquatic species because of use on rice. Exposure resulting from groundwater contamination is unlikely due to the fairly rapid soil metabolism of bifenox and its low leaching potential. The potential for leaching of the degradation products cannot be assessed from available data. A bioaccumulation factor of 50 was reported in mosquito fish after 3 days in a static model ecosystem. No other bioaccumulation data are available.

The greatest potential for exposure of wettable powder formulations is respiratory, during opening and pouring when "puff back" can occur. Splashing during dilution, mixing, and loading may result in dermal or ocular exposure.

Potential dermal exposure of the flowable and emulsifiable concentate formulations is greatest during mixing and loading, when splashing may occur. Such exposure can be minimized by the use of gloves and protective clothing during mixing and loading.

D. SUMMARY OF DATA GAPS

The data gaps for this chemical are: hydrolysis studies, photolysis studies, aerobic soil metabolism studies, aerobic and anaerobic aquatic metabolism, leaching studies, adsorption/desorption studies, water dispersal studies, terrestrial field, aquatic dissipation studies, rotational and irrigated crop studies, and fish accumulation studies.

The data requiremnts for manufacturing-use bifenox and the end use products are the same. Refer to Chapter III, Table 1.

VI. TOXICOLOGY

The Proposed Guidelines for Registering Pesticides in the United States sets forth conditions under which specific data would be required to support the registration of a product, specifying the standards for acceptable testing.

Toxicity data needed to determine potential adverse toxicological effects to humans and domestic animals as a result of the use of bifenox were generated by Industrial Bio-Test Laboratories (IBT) or were not available to the Agency.

IBT was one of the laboratories audited jointly by the EPA and the Food and Drug Administration under the Agency's Laboratory Audit Program. The function of this program was to ensure the reliability and integrity of data supplied to the Agency by pesticide manufacturers for purposes of supporting pesticide registrations and tolerances. The audit of the IBT Laboratories revealed a number of questionable scientific practices which led the Agency to require raw data for purposes of reevaluating all IBT studies used in support of pesticide registrations and tolerances. Review of the IBT toxicology data base on bifenox currently is being conducted by the Canadian government. Under the Registration Standards Program, Agency policy provides that IBT studies which have not yet been reviewed are considered administratively invalid and will not be included in the Registration Standard document. Thus, in the absence of the Canadian validation and the lack of any other toxicology data on bifenox, a detailed assessment of the hazard of bifenox to man and the environment cannot be made.

The data requirements needed to evaluate the continued registration of bifenox products to which this standard applies are listed in Chapter III, Tables 1-3.

VII. RESIDUE CHEMISTRY

A. INTRODUCTION

This chapter of the Registration Standard is concerned only with those formulations containing a single active ingredient. Conclusions or implications derived from data on such formulations do not necessarily apply to those having mutiple active ingredient.

The use pattern and restrictions for the formulations (F, EC and WP) of bifenox are used primarily for pre-emergent and some post-emergent weed control. This chemical is said to be particularly effective against broadleaf weeds.

According to current labels, the following additional instructions and restrictions apply when end-use products are used:

1. Reduce dosage in proportion to band areas actually treated.
2. Pre-emergence applications are not incorporated in the soil.
3. Post-emergence applications are made when the first leaves appear.
4. Cover crops can be planted if not grazed.

Specifically for rice:

1. Do not apply to second rice crop in areas where double cropping is practiced.
2. Do not use in areas where crayfish farming is practiced.
3. Do not use water from treated rice fields to irrigate upland crops.

5. Do not use bifenox on rice grown in California.

Specifically for sorghum:

1. Do not use bifenox on sweet sorghum or sorghum sudan.

B. RESIDUE CHEMISTRY PROFILE

The absorption, translocation and metabolism in plants have been investigated thoroughly in rice, corn, soybeans, and other plants. The metabolism of bifenox is adequately understood to be via reduction and/or hydrolysis to the corresponding amine and/or acid, followed by cleavage of the ether linkage to form various phenols which are further degraded and/or "bound", probably as gylcoside conjugates. Degradates include 2,4-dichlorophenol and p-nitrophenol.

^{14}C- metabolism data from a study on soybeans indicate little or no translocation from the plant root. Maximum ^{14}C- activity in leaves, stems and beans had an absorptivity level of only 0.03 ppm in tracer studies of wheat and rice involving foliar sprays of ^{14}C- materials. At the use rate, low levels of <0.05 ppm were found. Bifenox was found to metabolize rapidly in the rice plants.

Studies with rats fed ^{14}C- tagged bifenox and dogs fed cold bifenox showed little tissue accumulation. Large amounts of degradation or metabolism products were found in the liquid and solid waste of the dogs. Bifenox is rapidly metabolized and almost totally eliminated. Radio tracer studies on rats showed 90% of bifenox is eliminated within 48 hours.

Residue data from various crops treated at use rate and in excess of use rate showed <0.05 ppm, the practical method sensitivity. Adequate methods are available for residue determination and for enforcement purposes.

Residue studies on corn, rice, sorghum, soybeans, barley, oats, and wheat show that bifenox residues do not exceed the established pesticide tolerance of 0.05 ppm.

Since there was no evidence of bifenox residues in the animal feed items at the practical sensitivity (0.05 ppm) of the method there is no reasonable expectation of residues in meat, milk, or poultry and eggs.

There is no report of any regulatory action taken by the Food and Drug Administration with respect to residues of bifenox.

All residue data submitted for bifenox were obtained by the use of Mobil Chemical Method 70-72. This method consists of acetonitrile extraction, hexane partitioning, clean-up on mixed Florisil/alumina/Florex AA-LMV column followed by sweep co-distillation, and measurement by GLC equipped with halogen-specific microcoulmetric detection. The Florex-LMV is presently substituted for the specific Florex-AA-LMV.

Mobil Chemical Method 70-72 is found to have adequate specificity and is judged satisfactory for enforcement of established tolerances.

Over 200 crop samples were analyzed for residues of bifenox, using Mobil Chemical Method 70-72, sensitive to 0.05 ppm of the chemical. Samples were obtained from herbicide tests in 17 states, in Canada, Nicaragua and the Phillipines, and represented product use under a wide variety of climatic and soil conditions.

C. SUMMARY OF DATA GAPS

Presently, all data requirements have been fulfilled. Refer to Chapter III, Table 1, of this Standard.

VIII. ECOLOGICAL EFFECTS

A. ECOLOGICAL EFFECTS PROFILE

1. Fish and Wildlife

Available data are insufficient to assess the toxicological effects of technical bifenox on freshwater fish (warmwater or coldwater), freshwater aquatic invertebrates, estuarine and marine organisms, and birds due to deviations from acceptable protocols.

Data submitted to the Agency for review to determine the toxicity of bifenox to birds are IBT data. These studies are considered administratively invalid and cannot be included in a Registration Standard.

The 40% flowable bifenox end-use product is moderately toxic to aquatic invertebrates. The 48 hour acute LC_{50} for daphnia was 1.8 mg/L and the 96 hour LC_{50} for pink shrimp was 2.6 ppm (LeBlanc 1976, MRID 00003366).

Environmental fate data, chronic fish (fresh and estuarine) and/or marine and freshwater invertebrates studies may be required after review of the above acute toxicity studies on technical bifenox.

2. Plants - Phytotoxicity

Emulsifiable Concentrate

Available data concerning the phytotoxic effects of bifenox emulsifiable concentrate on various crops indicate that the no-effect levels for post-emergence application to barley, oats, and wheat varied from less than .5 to 1 lb. ai/A. The no-effect level for postemergent application to rice was less than 1 lb. ai/A. The no-effect levels for pre-emergence application to corn and rice varied from less than 2 to 2.5 lb. ai/A. Sorghum suffered 10% injury following pre-emergence applications of 1.5 to 2 lb. ai/A and the no-effect level for a similar application to soybeans was 1 to 2 lb. ai/A.

Flowable

The no-effect level for pre-plant incorporation (PPI) of flowable bifenox to corn, sorghum, and soybeans, wheat, and oats was less than 2 lb. ai/A. At 2 lb. ai/A PPI, alfalfa was damaged 65% and clover 45%. The no-effect level to rice for a pre-emergence application was less than 2.5 lb. ai/A and less than 2 lb. ai/A for a post-emergence application. Pre-emergence applications of 1.5 to 2 lb. ai/A resulted in a 10% injury to sorghum or soybeans, although some soybean tests resulted in damage at rates as low as 0.5 lb. ai/A. A post-emergence application of 1 lb. ai/A has no effect on wheat.

Granular

Although the 10% granular dust is no longer manufactured, a study showed that a 3 lb. ai/A post-emergence application resulted in a 10% injury to rice.

Wettable Powder

The no-effect level for pre-emergence application of wettable powder bifenox to corn or sorghum was 1.5 lb. ai/A and varied from less than 1.6 to 3.75 lb. ai/A for rice. The no-effect level for pre-emergence treatment on soybeans varied from less than 1 to 2 lb. ai/A. Postemergence application of 1 lb. ai/A caused no injury to wheat and 1.5 lb. ai/A caused no injury to black walnut or white pine, but the no-effect level for a similar application to tulip poplar was less than 0.75 lb. The no-effect levels for preplant incorporation treatment were 2 lbs. ai/A for wheat and less than 2 lbs. for oats, sorghum, soybeans and corn. Clover and alfalfa suffered up to 65% damage with a PPI of 2 lb. ai/A. The no-effect level for tobacco PPI varied from less than 1.5 to 6.1 ai/A.

B. HAZARD ASSESSMENT

1. Manufacturing-use Bifenox

A hazard assessment is not conducted on the technical.

2. End Use Products

The available data are insufficient to assess the potential hazard of bifenox in the environment. The use of bifenox on such crops as rice exposes aquatic organisms to a potential hazard. Until acceptable toxicity studies on representative organisms and adequate fate data are submitted, a hazard assessment will not be conducted.

3. Non-Target Plant

Although sufficient information exists to characterize the hazard of bifenox to nontarget area crops, little information is available concerning the effects to other nontarget area plants. Bifenox is registered for use on corn, nursery seedbeds, rice, sorghum, soybeans, and wheat. Label rates for these crops allow for some temporary injury, but label cautions and the acceptable nature of the injury indicate that bifenox is not hazardous enough to these crops to be of concern. Ninety-five percent of bifenox is currently used on soybeans, rice and sorghum. It seems unlikely that large areas of nontarget plants would be exposed, although some drift to adjacent land strips resulting from normal application patterns would be expected.

The effect of bifenox on nontarget aquatic plant cannot be assessed at this time due to the lack of toxicity data.

C. SUMMARY OF DATA GAPS

1. Manufacturing-Use Bifenox

The ecological effects data gaps for technical bifenox are as follows: one avian single-dose oral LD_{50} (mallard duck or bobwhite quail); two avian dietary LC_{50} studies (mallard duck and bobwhite quail); two 96-hour LC_{50} tests on freshwater fish (rainbow trout and bluegill sunfish); one 48-hour acute toxicity study on an aquatic invertebrate (*Daphnia magna*); one estuarine and marine organism toxicity study (96-hour LC_{50} oyster embryolarva or a 96-hour EC_{50} shell deposition for molluscs).

The data requirements for a seed germination, aquatic marcrophytes and algae study on technical bifenox will be required within two years.

2. End Use Products

The ecological effects data gaps for the 80% wettable powder and the 21% emulsifiable concentrate are fish acute LC_{50} on one coldwater (rainbow trout) and one warmwater fish (bluegill sunfish), a 96-hour acute toxicity test on an aquatic invertebrate (Daphnia), estuarine and marine organisms toxicity study (preferably 96-hour LC_{50} for shrimp and fish, and either 48-hour LC_{50} for embryolarvae or 96-hour EC_{50} shell deposition for molluscs.

Additional acute toxicity testing on the 40% flowable is required on one coldwater fish (rainbow trout) and one warmwater fish (bluegill), and one estuarine fish. A 48-hour oyster embryolarvae study is also required.

The data requirements needed to evaluate the continued registration of bifenox products to which this Standard applies are listed in Chapter III, Tables 2 and 3.

GUIDE TO USE OF BIBLIOGRAPHY

Guide to Use of This Bibliography

1. Content of Bibliography. This bibliography contains citations of all the studies reviewed by EPA in arriving at the positions and conclusions stated elsewhere in this standard. The bibliography is divided into 3 sections: (1) citations that contributed information useful to the review of the chemical and considered to be part of the data base supporting registrations under the standard, (2) citations examined and judged to be inappropriate for use in developing the standard, and (3) standard reference material. Primary sources for studies in this bibliography has been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions, and the published technical literature.

2. Units of Entry. The unit of entry in this bibligraphy is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the agency, the Agency has sought to identify documents at a level parallel to a published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purpose of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. Identification of Entries. The entries in this bibliography are sorted by author, date of the document, and title. Each entry bears, to the left of the citation proper, an eight-digit numeric identifier. This number is unique to the citations, and should be used at any time specific reference is required. This number is called the "Master Record Identifier", or "MRID". It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted data; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. This is also to be used wheneer a specific reference is needed.

4. Form of the Entry. In addition to the Master Record Identifier (MRID:), each entry consists of a bibliographic citation containing standard elements followed, in the case of materials submitted to EPA, by a description of th earliest known submission. The bibliographic convention used reflect the standards for the American National Standards Institute (ANSI), expanded to provide for certain special needs. Some explanatory notes of specific elements follow:

   a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identificable laboratory or testing facility as author. As a last resort, the Agency has shown the first known submitter as author.

   b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

   c. Title. This is the third element in the citation. In some cases it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

   d. Trailing Parenthesis. For studies submitted to us in the past, the trailing parenthesis include (in addition to any self-explanatory text) the following elements describing the earliest known submission.

      (1) Submission Date. Immediately following the word 'received' appears the date of the earliest known submission.

      (2) Administrative Number. The next element, immediately following the word 'under', is the registration number, experimental permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter, following the phrase 'submitted by'. When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification. The final element in the trailing parenthesis identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol 'CDL', standing for "Company Data Library". This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 1234456-B; the 26th, 123456-Z; and the 27th 123456-AA.

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